UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	
THIS DOCUMENT RELATES TO:	MDL No. 1456
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., Civil Action No. 06-11337-PBS;	Civil Action No. 01-12257-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al., Civil Action No. 05-11084-PBS; and	Hon. Patti B. Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp., et al., Civil Action No. 07-10248-PBS	

UNITED STATES' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS COMMON TO ALL DEFENDANTS

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Pursuant to Local Rule 56.1, the United States hereby submits its Statement of Undisputed Material Facts Applicable to all Defendants in Support of its Motions for Partial Summary Judgment and its Oppositions to Defendants' Motions for Summary Judgment . Facts specific to each Defendant are set out in separate Statements of Undisputed Facts (Separate Statements) filed herewith. To the extent any statement of fact herein is genuinely disputed, the United States reserves the right to argue that the disputed fact is not material.

I. THE MEDICARE PART B PROGRAM

A . Medicare Part B Reimbursement Methodology

1. Medicare is a federally-funded health insurance program for people age 65 or older, people under age 65 with certain disabilities, and people of all ages with End-Stage Renal Disease (permanent kidney failure requiring dialysis or a kidney transplant). 42 U.S.C. § 1395 *et seq*. Medicare Part A helps cover inpatient care in hospitals, including critical access hospitals, hospice, skilled nursing facilities, and some home health care. 42 U.S.C. §§ 1395c-1395i-4. Medicare Part B helps cover doctors' services and outpatient care. 42 U.S.C. §§ 1395j to 1395w-4. It also covers some other medical services that Part A does not cover, such as some of the services of physical and occupational therapists, and some home health care not covered by Medicare Part A. Medicare Part B also covers certain drugs. 42 C.F.R. §§ 405.517, 414.701, 410.26 .

2. Since the early 1990s, Medicare Part B has typically paid for covered drugs using average wholesale prices (AWP) published in the Red Book. (Common Declaration of George B. Henderson in Support of Motions for Partial Summary Judgment (hereinafter, Henderson Common) Exhibit 1)

3. Since at least the 1970s, Medicare Part B has covered items of durable medical equipment (DME), including drugs used in conjunction with DME. 42 C.F.R. §§ 414.200, 414.701.

4. Medicare Part B classifies and pays for covered drugs through a coding system called the Healthcare Common Procedure Coding System (HCPCS). Medicare assigns individual HCPCS codes for most drugs. These codes have usually included a prefix of "J" or "K." One HCPCS code may cover a generic drug manufactured by a variety of manufacturers. The HCPCS codes are used in the determination of allowable amounts, and Medicare Part B payments for most covered drugs are made on the basis of HCPCS codes. (Henderson Common Exhibit 2; Henderson Common Exhibit 3 (Declaration of Carolyn Helton (hereinafter, Helton Decl.), ¶ 7)

5. The Medicare program is administered by the Department of Health and Human services through the Centers for Medicare and Medicaid services (CMS, formerly known as the Healthcare Financing Administration). CMS uses fiscal intermediaries, also called carriers, to perform bill processing and benefit payment functions for the Medicare program. 42 U.S.C. § 1395u. In this capacity, the Contractors act on behalf of CMS. 42 C.F.R. § 421.5(b). Most providers of services (such as hospitals, skilled nursing facilities, home health care providers) submit bills to these intermediaries, which determine whether the services are covered under Medicare and determine correct payment amounts. 52 Fed. Reg. 37526,37527 (October 7, 1987).

6. In 1993, HCFA established four Durable Medical Equipment Regional Carriers (DMERCs) and assigned DME claims administration functions to those carriers. 58 Fed. Reg.

60789 (November 18, 1993); 57 Fed. Reg. 27290 (June 18, 1992). Each DMERC performs DME claims administration functions for a region of the country. 42 C.F.R. § 421.210. During the pertinent time period the four regional DMERCs were known as Travelers Insurance Company/HealthNow (DMERC Region A)[1]; AdminaStar Federal (DMERC Region B); Palmetto GBA (DMERC Region C); and CIGNA (DMERC Region D). 58 Fed. Reg. 60789 (November 18, 1993).

7. During the relevant time period, HCFA and CMS periodically issued program memoranda to the carriers and DMERCs providing instructions concerning the administration of the Medicare program. (Henderson Common Exhibit 4 (10/11/2007 Niemann Dep.), at 365:9-365:22; Henderson Common Exhibit 5 (4/25/2007 Tawes Dep.), at 435:4 - 435:6)

8. Prior to January 1, 1992, there was no specific regulation or statutory provision that governed Medicare payments for drugs, instead, the government set payment limits based on the overarching Medicare Part B provisions, limiting payments under Part B to a "reasonable charge." *See* 42 U.S.C. §§ 1395l, 1395u(o). As for "reasonable charge," Congress wanted Medicare payments to be limited by what a physician "customarily" charged patients for a particular service or the "prevailing" charges for a service in a given locality. S. Rep. No. 404, 89th Cong., 1st Sess., reprinted in 1965 U.S.C.A.A.N. 1943, 1984-85.

9. HHS promulgated its first Medicare drug payment regulation in 1991. The regulation stated:

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[1] The DMERC-A contract was initially awarded to Travelers Insurance Company. Through a series of corporate transactions, United Healthcare became the successor-in-interest to Travelers and served as the DMERC until September 2000, when HealthNow was awarded the DMERC contract for Region A. 70 Fed. Reg. 9232 (February 25, 2005).

> § 405.517 Payment for drugs that are not paid on a cost or prospective payment basis.
>
> (a) Applicability. Payment for a drug that is not paid on a cost or prospective payment basis is determined by the standard methodology described in paragraph (b) of this section. Examples of when this procedure applies includes a drug furnished incident to a physician's service and a drug furnished by an independent dialysis facility that is not included in the ESRD composite rate set forth in § 413.170© of this chapter.
>
> (b) Methodology. Payment for a drug described in paragraph (a) of this section is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. The estimated acquisition cost is determined based on surveys of the actual invoice prices paid for the drug. In calculating the estimated acquisition cost of a drug, the carrier may consider factors such as inventory, waste, and spoilage.
>
> © Multiple-Source drugs. For multiple-source drugs, payment is based on the lower of the estimated acquisition cost described in paragraph (b) of this section or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.

56 Fed. Reg. 59502, 59621 (Nov. 25, 1991).

10. The surveys contemplated by subsection (b) were not completed. (Henderson Common Exhibit 6 (6/20/2007 Vito Dep.), at 338:4 - 339:15)

11. From 1992 through December 31, 1997, Medicare paid for Part B covered multiple-source drugs based on the lower of the provider's billed charge or the median AWP of the generic forms of the drug. 56 Fed. Reg. 59502, 59621 (November 25, 1991); (Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 4, 13)

12. From January 1, 1998, until December 31, 1998, Medicare based its reimbursement for all generic forms of a drug at 95% of the median AWP for the drug. Balanced Budget Act of 1997, 42 U.S.C. § 1395u(o); 42 C.F.R. § 405.517 (1998).

13. From January 1, 1999, through December 31, 2003, the Medicare paid for Part B covered multiple-source drugs based on (a) the amount submitted by the provider on the claim, or (b) 95 percent of the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological. That median then served as the basis for reimbursing for all drugs within a HCPCS code, regardless of manufacturer. 42 U.S.C. § 1395u(o); 42 C.F.R. § 405.517 (1999-2004); (Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 3, 13)

14. According to testimony from the former CMS Director of Payment Policy, comparisons between the Veterans Administration (VA) drug purchasing data and Medicare reimbursement were not useful to CMS officials because CMS, unlike the VA, was not purchasing drugs directly from manufacturers. In addition, the VA purchased drugs in much larger volumes than Medicare providers and could leverage discounts directly from manufacturers. (Henderson Common Exhibit 7 (4/23/ 2007 Booth Dep.), at 43:20-44:5, 212:20 - 213:18, 216:17 - 218:12); Henderson Common Exhibit 8)

15. The pricing analyst for CIGNA, the DMERC for Region D, during the relevant time was Carolyn Helton. She determined the allowable amounts for DME drugs on behalf of CIGNA during the time in question. The source of CIGNA's pricing information was the Red Book, unless that publication did not publish the information needed for a particular product. (Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 9, 10, 18)

16. To determine the median AWP of the generic sources of a drug, Ms. Helton used the Red Book to find the products that fit within the narrative description of the pertinent HCPCS code. (Henderson Common Exhibit 3 (Helton Decl.), ¶ 10) She recorded the product

information, including the published AWPs, in an array (or she updated a pre-existing array), and converted the published package AWP price in the Red Book to a per-unit price. If there was only one NDC with a published AWP in the array, she selected that price as the median. If there was an odd number of NDCs in the array, she selected the middle NDC and its corresponding price. If there was an even number of NDCs in the array, she took the average of the middle two NDCs' prices to achieve a median. (*Id*., ¶ 11)

B. "DOJ AWPs"

17. On or around September 8, 2000, CMS sent Program Memorandum Transmittal AB-00-86 to Medicare Part B carriers, including the DMERCs, providing them with alternative wholesale price information developed jointly by the Department of Justice and the National Association of Medicaid Fraud Control Units (NAMFCU). (Abbott Ex. AP; Roxane Tab 118; Reid Decl. Ex. 181) The price information covered 32 different drugs, including some of those at issue in the instant cases, compiled mainly from wholesaler catalogs. (*Id*. at 1) (The parties have referred to the alternative AWPs as the DOJ AWPs, although in reality the information consisted simply of prices considered generally and currently paid in the marketplace.) The Transmittal instructed the carriers to consider those alternate wholesale prices in determining Medicare reimbursement amounts. (*Id*.)

18. CMS did retract the September 2000 Program Memorandum. (Roxane Tab 121 (November 17, 2000 Program Memorandum to Carriers and Intermediaries)) However, it was not a rejection of the need for pricing information pricing information reflective of what was generally and currently paid in the marketplace. A subsequent HCFA program memorandum made clear that the purpose was to give the General Accounting Office (GAO) time to review

Medicare payment policies and to make specific recommendations to the Secretary and Congress as to how to revise drug payment methodologies. (Abbott Ex. BD (May 3, 2001 Program Memorandum from HCFA to Carriers and Intermediaries))

19. Indeed, the Benefits Improvement and Protection Act of 2000 arose out of efforts by Congress to stop what one representative termed "illegal behavior" and an "outrage." (Henderson Common Exhibit 9 (Medicare Payments for Currently Covered Prescription Drugs: Hearing Before the Subcomm. on Health of the H. Comm. on Ways and Means, 107th Cong. 7 (2002) (statement of Rep. Stark, Member, House Comm. on Ways and Means))

20. On September 21, 2001, the GAO issued the report as directed by Congress. The GAO report recommended:

> Establish Medicare payment levels for part-B prescription drugs and their delivery and administration that are more closely related to their costs. Payments for drugs should be set at levels that reflect actual market transaction prices and the likely acquisition cost to providers.

(Henderson Common Exhibit 39 (Payments for Covered Outpatient Drugs Exceed Providers' Costs, GAO-01-1118, September 21, 2001))

II. THE MEDICAID PROGRAM

21. Medicaid is a federal-state program to assist the poor, elderly, and disabled in obtaining medical care. 42 C.F.R. § 430.0 (2009). Under the Medicaid Act, which is Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 - 1396v, the federal government provides financial support to states that establish and administer state Medicaid programs in accordance with federal law through a state plan approved by the U.S. Department of Health and Human Services ("HHS"). 42 U.S.C. § 1396; 42 C.F.R. §§ 430.0, 430.10 - 430.20 (2009). One

requirement is that the state have a State Plan that includes a methodology for reimbursing health care providers. 42 U.S.C. §§ 1396a(a), 1396d(a). A declaration authenticating the state plans produced by the United States in this case is attached to the Henderson Common Declaration. (Henderson Common Exhibit 44 (Declaration of William S. Lasowski))

22. Federal regulations require that state Medicaid programs' payment for drugs not subject to Federal Upper Limits not exceed, in the aggregate, the estimated acquisition cost of the drug plus a reasonable dispensing fee established by the agency. 42 C.F.R. § 447.331. For purposes of this regulation, the term "estimated acquisition cost" was defined as "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. § 447.301.

23. State Medicaid programs required accurate, current and comprehensive pricing information in order to process many hundreds of thousands if not millions of claims for reimbursement on many thousands of different products. (Henderson Common Exhibit 10 (9/23/2008 Hillblom Dep. (California)), at 94:22 - 95:18); Henderson Common Exhibit 11 (12/15/2008 Dubberly Dep. (Georgia)), at 61:5-62:16; Henderson Common Exhibit 12 (11/18/2008 Parker Dep. (Illinois)), at 62:5 - 64:9, 67:5 -68:16; Henderson Common Exhibit 13 (12/3/2008 Cheloha Dep. (Nebraska)), at 341:7 - 346:18; Henderson Common Exhibit 14 (12/2/2008 Vaccaro Dep. (New Jersey)), at 70:3 -72:13; Henderson Common Exhibit 15 (12/15/2008 Stevens Dep. (New Mexico)), at 312:4 -315:22; Henderson Common Exhibit 16 (10/21/2008 Weeks Dep. (North Carolina)), at 101:2 - 104:21; Henderson Common Exhibit 17

(12/15/2008 Rugg Dep., (Vermont)), at 357:1 - 358:22; Henderson Common Exhibit 18 (12/4/2008 Hayashi Dep. (Virginia)), at 27:6 -29:11)

24. State Medicaid programs relied on published AWPs (and in some cases wholesale acquisition cost (WAC), *see infra* ¶¶ 30, 34 and 36-84) to estimate acquisition costs and process claims for reimbursement. It would not have been possible for States to process Medicaid claims without relying on AWPs and WACs published by the compendia. (Henderson Common Exhibit 19 (12/10/2008 Bridges Dep. (Arkansas)), at 43:16 - 44:21, 63:12 - 64:17; Henderson Common Exhibit 20 (12/9/2008 Fine Dep. (Maryland)), at 48:11 - 50:15; Henderson Common Exhibit 13 (12/3/2008 Cheloha Dep. (Nebraska)), at 341:12 - 345:11, 348:12 - 350:10; Henderson Common Exhibit 21 (10/28/2008 Farrand Dep. (New Hampshire)), at 282:7 - 284:22; Henderson Common Exhibit 22 (10/29/2008 Clifford Dep. (New Hampshire)), at 203:9 - 203:12; Henderson Common Exhibit 14 (12/2/2008 Vaccaro Dep. (New Jersey)), at 70:3 -72:16; Henderson Common Exhibit 16 (10/21/2008 Weeks Dep. (North Carolina)), at 43:2 - 44:22; Henderson Common Exhibit 17 (12/15/2008 Rugg Dep.(Vermont)), at 358:1 - 358:22; Henderson Common Exhibit 23 (11/24/08 Hautea-Wimpee Dep. (Washington)), at 137:1 - 138:21)

A. *State Payment Methodologies*

25. The firm Myers and Stauffer LC has provided support to the United States' expert witness Mark G. Duggan, Ph.D. As part of that support, Myers and Stauffer gathered information concerning the methodologies used by the Medicaid programs of 48 States and the District of Columbia (the Covered States) to reimburse pharmacy providers for prescription drugs. (Henderson Common Exhibit 24 (Declaration of Kristopher Knerr (Knerr Decl.) ¶¶ 4-12). The information gathered by Myers and Stauffer was described in a series of summaries that

drug payment methodologies for each state in the damages reports (Covered States). The summaries and all supporting information were produced to the defendants in connection with the United States' expert disclosures.

26. Subsequent to those disclosures, Myers and Stauffer has updated the methodology summaries to reflect information obtained in discovery. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 13-14) All additional materials relied upon by Myers and Stauffer in connection with the updating of the methodology summaries were produced to the defendants on July 24, 2009. (*Id.*, ¶ 13)

27. In preparing the summaries, Myers and Stauffer relied upon (a) State Plan Amendments obtained from CMS through DOJ; (b) deposition testimony (including testimony from state officials regarding the actual implementation of the payment methodology), deposition exhibits, and documents produced by Covered States pursuant to subpoenas; © state statutes, regulations and declarations; (d) annual publications of the National Pharmaceutical Council (NPC), *Pharmaceutical Benefits Under State Medical Assistance Programs*, from 1990 through 2005/2006; (e) communications with officials of State Medicaid agencies; and (f) policy manuals, provider bulletins, and other similar materials available on state Medicaid agency websites. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 8-10 and 12-13)

28. The methodology summaries are Attachment 1 to Knerr Decl. The information in each summary accurately summarizes the underlying data that was gathered by Myers and Stauffer. (Henderson Common Exhibit 24, (Knerr Decl.), ¶ 5)

29. Currently all Covered States except for Indiana reimburse pharmacy providers for prescription drugs under a "lower of" methodology in which payment is made based, at least in

part, on the lower of (a) the State's estimated acquisition cost (EAC) plus a dispensing fee, (b) the pharmacy's usual and customary charge (U&C) (sometimes referred to as the "billed amount"), or (c) the Federal Upper Limit (FUL) established by CMS pursuant to 42 C.F.R. § 447.332; (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 18) Indiana recently eliminated the FUL from its methodology. (*Id.*)

30. For the period 1991 to the present, each Covered State used AWP as the primary basis for determining the EAC component of their drug payment methodology, during at least part of that period; 42 of the Covered States used AWP as the primary basis for determining the EAC component of their State's drug payment methodology for the entire time period of 1991 to present. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 24a). The remaining Covered States used WAC or a combination of AWP and WAC as the basis for determining the EAC component of their state's drug payment methodology. (*Id.*, ¶ 24b)

31. During the period 1991 to the present, only six Covered States have deviated from the methodology described in the paragraph 29, above: (1) Delaware used Actual Acquisition Cost before May 1, 1997; (2) Michigan used Actual Acquisition Cost, with a limit based on AWP, before September 15, 1995; and (3) Alaska, New York, Arkansas and Massachusetts, each for specific periods of time, did not include EAC in the "lower of" algorithms when the drug was subject to a FUL. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 19)

32. During the period 1991 to the present, 42 of the Covered States have implemented a State Maximum Allowable Cost (SMAC) (sometime under different names) feature. A SMAC is an upper limit established by the State, similar to the FUL, but often determined based on criteria different than the FUL. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 20, 24f)

Twenty two of these Covered States have implemented a SMAC program during the entire time period. (*Id*., ¶ 24f) In all of these Covered States, the SMAC program is incorporated into the "lower of" methodology described above, except that Hawaii does not apply the SMAC if an FUL is in place. (*Id*., ¶¶ 20, 24e-f)

33. Twenty-five Covered States add to their "lower of" algorithm, for at least some of the time period, the wholesale pricing information provided in 2000 by the Department of Justice and the National Association of Medicaid Fraud Control Units and published by First DataBank. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 21)

34. Forty-three Covered States use First DataBank or First DataBank together with Medispan or Red Book as their primary source of information for determining EAC. Of the remaining six Covered States, five use MediSpan as their primary source for determining EAC, and one State uses Red Book for determining EAC. Some Covered States have changed the compendia they use for their prescription pricing, as noted in the respective Myers and Stauffer summaries. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 24c)

35. The following paragraphs 36 through 85, concerning the accuracy of State methodology summaries, refer to the summaries in Attachment 1 to the Knerr Decl. The "supporting materials" means the supporting materials referenced in ¶¶ 5 and 12-13 of the Knerr Declaration.

36. The summary for the State of Alabama is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

37. The summary for the State of Alaska is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

38. The summary for the State of Arkansas is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

39. The summary for the State of California is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

40. The summary for the State of Colorado is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

41. The summary for the State of Connecticut is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

42. The summary for the State of Delaware is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

43. The summary for the State of Florida is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

44. The summary for the State of Georgia is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

45. The summary for the State of Hawaii is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

46. The summary for the State of Idaho is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

47. The summary for the State of Illinois is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

48. The summary for the State of Indiana is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

49. The summary for the State of Iowa is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

50. The summary for the State of Kansas is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

51. The summary for the Commonwealth of Kentucky is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

52. The summary for the State of Louisiana is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

53. The summary for the State of Maine is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

54. The summary for the State of Maryland is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

55. The summary for the Commonwealth of Massachusetts is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

56. The summary for the State of Michigan is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

57. The summary for the State of Minnesota is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

58. The summary for the State of Mississippi is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

59. The summary for the State of Missouri is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

60. The summary for the State of Montana is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

61. The summary for the State of Nebraska is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

62. The summary for the State of Nevada is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

63. The summary for the State of New Hampshire is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

64. The summary for the State of New Jersey is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

65. The summary for the State of New Mexico is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

66. The summary for the State of New York is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

67. The summary for the State of North Carolina is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

68. The summary for the State of North Dakota is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

69. The summary for the State of Oklahoma is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

70. The summary for the State of Oregon is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

71. The summary for the Commonwealth of Pennsylvania is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

72. The summary for the State of Rhode Island is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

73. The summary for the State of South Carolina is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

74. The summary for the State of South Dakota is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

75. The summary for the State of Tennessee is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

76. The summary for the State of Texas is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

77. The summary for the State of Utah is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

78. The summary for the State of Vermont is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

79. The summary for the Commonwealth of Virginia is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

80. The summary for the State of Washington is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

81. The summary for the State of West Virginia is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

82. The summary for the State of Wisconsin is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

83. The summary for the State of Wyoming is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

84. The summary for the District of Columbia is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

B. *State Claims To the Federal Government For Federal Medicaid Monies*

85. States request federal Medicaid funds on a quarterly basis. Henderson Common Exhibit 25 (Declaration of Kristin A. Fan (Fan Decl.), ¶ 5) The process generally begins 45 days before the upcoming quarter begins, with each state submitting to CMS a budget of what it projects the state will spend during the upcoming quarter. *Id*.; 42 C.F.R. § 430.30(b). The state Medicaid official provides the information electronically using a Form CMS-37. (*Id.*, ¶ 5) Along with the overall funding request, the state will provide estimates of various types service, including drug costs. *Id*. Further, the CMS-37 includes a certification that states in part:

> The fiscal year budget estimates only include expenditures under the Medicaid program under title XIX of the Social Security Act (the Act), and as applicable, under the State Children's Health Insurance Program (SCHIP) under title XXI of the Act, that are allowable in accordance with applicable implementing Federal, state, and local statutes, regulations, policies, and the state plan approved by the Secretary and in effect during the fiscal year under title XIX of the Act for the Medicaid program, and as applicable, under title XXI of the Act for the SCHIP. The budget estimates are based upon the most reliable information available to the state.

Id.

86. A state's budget estimate for a given quarter is normally based on the state's Medicaid expenditures in prior quarters. (Henderson Common Exhibit 25 (Fan Decl.), ¶ 6) Therefore, if drug expenditures in prior quarters are improperly inflated, this would likely cause, absent an adjustment, the budget estimate for a subsequent quarter to be inflated. *Id*.

87. The CMS 37 form is sent to the appropriate regional CMS office. (Henderson Common Exhibit 25 (Fan Decl.), ¶ 7); 42 C.F.R. § 430.30(b), (d). Upon receipt, regional office staff will review the form and make recommendations to the CMS central office as to whether the state funding request should be approved, approved with adjustments, or denied. 42 C.F.R.

§ 430.30(d); *Id.*, ¶ 7) The CMS central office reviews the regional analyst's recommendations. (*Id.*, ¶ 7) In deciding what funding level to approve for the following quarter, the CMS central office "considers the State's estimates, the regional office recommendations and any other relevant information, including any adjustments to be made under paragraph (d)(2) of this section, and computes the grant." (*Id.*; 42 C.F.R. § 430.30(d)(2)) In determining whether any adjustments should be made under subsection (d)(2) of the regulation, the central office examines any expenditures from previous quarters. (*Id.*, ¶ 7; 42 C.F.R. § 430.30(d)(2)) Once the funding request is approved, the state can draw down the federal monies on a federal letter of credit for the allotted amount as costs are incurred. (*Id.*, ¶ 7) The State draws down federal funds through a commercial bank and the Federal Reserve System. *Id.*

88. Section 430.30(d)(3), 42 C.F.R., provides that the grant award "authorizes the State to draw Federal funds as needed to pay the Federal share of disbursements." (Emphasis added). It is CMS's position that the state's quarterly federal Medicaid award is only to be used to reimburse Medicaid providers for actual payments. (Henderson Common Exhibit 25 (Fan Decl.), ¶ 8) In practice, a state draws down federal funds as actual payments are made by the State to Medicaid providers, including pharmacies and physicians seeking payment for drugs. *Id.* Thus, if a state overpays providers because of false provider claims, the state's draw-down on the letter of credit for the federal share will be affected, unless an adjustment is made. (*Id.*, ¶ 8)

89. After each calendar quarter, the state must submit to CMS a reconciliation of its actual Medicaid expenditures against the monetary advance made on the basis of the Form 37. 42 C.F.R. § 430.30©. The state electronically submits this information using a Form CMS-64. A State submitting the Form CMS 64 makes a certification that includes the following:

> I certify that:
>
> 1. I am the executive officer of the state agency or his/her designate authorized by the state to submit this form.
>
> 2. This report only includes expenditures under the Medicaid program under Title XIX of the Social Security Act (the Act), and as applicable, under the State Children's Health Insurance Program (SCHIP) under Title XIX of the Quarter Ended indicated above under Title XXI of the Act.
>
> 3. The expenditures included in this report are based on the state's accounting of actual recorded expenditures, and are not based on estimates.

(Henderson Common Exhibit 25 (Fan Decl.), ¶ 9)

90. The CMS web site provides an explanation of the Form CMS-64. Centers for Medicare and Medicaid Services, Medicaid Budget and Expenditure System (Medicaid Quarterly Expense Report), available at http://www.cms.hhs.gov/MedicaidBudgetExpendSystem/02_CMS64.asp. It states in part:

> The amounts reported on Form CMS-64 and its attachments must be actual expenditures for which all supporting documentation, in readily reviewable form, has been compiled and is available immediately at the time the claim is filed. Form CMS-64 is a statement of expenditures for which states are entitled to Federal reimbursement under Title XIX and which reconciles the monetary advance made on the basis of Form CMS-37 filed previously for the same quarter. Consequently, the amount claimed on the Form CMS-64 is a summary of expenditures derived from source documents such as invoices, cost reports and eligibility records.

(Henderson Common Exhibit 25 (Fan Decl.), ¶ 10)

91. The information in the Form CMS-64 is a source of information used in adjusting future Form-37 funding requests. (Henderson Common Exhibit 25 (Fan Decl.), ¶ 11; 42 C.F.R.

§ 430.30(d)(2)) If CMS believes that it has overpaid a state based on its review of the Form-64, or otherwise, CMS may adjust future authorizations to offset the overpayment or seek to recover the amount overpaid. (42. U.S.C. § 1396b(d)(5); *Id.*, ¶ 11) While federal funding is made available prospectively to state Medicaid programs, the quarterly funding level for a state's Medicaid program is directly determined based on the state's actual, quarterly Medicaid expenditures. (*Id.*, ¶ 11)

C. The Role of Price Compendia in Medicaid Drug Payment

92. Many third-party payors, including state, federal government and private health plans, use database products from national drug pricing compendia in determining their payment levels for drugs eligible for payment under their benefit plans. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 25-84;) *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 263 F. Supp.2d 172, 178 (D. Mass. 2003)) In the separate statements of undisputed facts as to each defendant the plaintiffs list the AWPs reported by FDB for each defendant's Subject Drugs. In all cases in which a Defendant has produced records showing the amounts it reported to FDB as either its AWPs or other reported prices (*e.g.*, list price or WAC) used to determine the AWP by application of a fixed markup.

93. A corporate designee for one of the compendia publishers, Red Book, testified that the manufacturers controlled the prices published in the Red Book. Kristin Minne testified that AWP was a required Red Book field until early 2003. (Henderson Common Exhibit 26 (11/18/08 Minne Dep.), at 158:9 -159:1) AWPs were provided to Red Book by the Defendants, and those manufacturer-supplied AWPs were then entered into the pricing database. (*Id.*, 158:9 - 159:1) Annually, Red Book sends a Product Listing Verification (PLV) form to each

manufacturer. (*Id*., 84:11-87:1) The PLV includes a print out of the manufacturer's drugs as they are currently listed by Red Book, and it requests that the manufacturer verify and confirm that their products' pricing information is accurate. (*Id*., 95:6 - 96:14)

94. As of early 2003, Red Book implemented a new AWP Policy, in which manufacturers were no longer required to report their AWPs. If they chose not to report an AWP, Red Book would calculate and publish an AWP based on a percentage markup from the manufacturer's reported WAC or DP. Manufacturers were notified of what this standard mark-up formula would be. (Henderson Common Exhibit 26 (11/18/08 Minne Dep.), at 159:11 - 160:1) Manufacturers choosing to report only a WAC or DP provided guidance to Red Book on how to calculate an AWP for their product. (*Id.*, 171:2 - 171:18)

III. 2003 OIG COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS

95. On October 3, 2002, the Office of Inspector General for the Department of Health and Human Services published "Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers." 67 Fed. Reg. 62057-62067 (Oct. 3, 2002). The Draft Guidance identified "major risk areas for pharmaceutical manufacturers: (1) Integrity of data used by state and Federal governments to establish payment . . . ." 67 Fed. Reg. at 62060. The Draft Guidance further stated:

> Many Federal and state health care programs establish reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act, if government reimbursement (including, but not limited to,

> reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately.

67 Fed. Reg. at 62060.

96. On May 5, 2003, the Office of Inspector General for the Department of Health and Human Services published final "OIG Compliance Program Guidance for Pharmaceutical Manufacturers." 68 Fed. Reg. 23731-23743 (May 5, 2003). The Guidance identified "major potential risk areas for pharmaceutical manufacturers: (1) Integrity of data used by state and Federal governments to establish payment . . . ." 68 Fed. Reg. at 23732. The Guidance identified "Specific Risk Areas" for pharmaceutical manufacturers, including "[i]ntegrity of data used by state and Federal governments to establish payment amounts." 68 Fed. Reg. at 23733. The Guidance further stated:

> Many Federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately."

Id.

IV. CONFIDENTIALITY OF AMP AND URA INFORMATION

97. Pursuant to the Medicaid Drug Rebate Statute (Rebate Statute), pharmaceutical manufacturers (including Abbott, Dey and Roxane) are required to enter into a national Medicaid Rebate Agreement with the CMS. 42 U.S.C. § 1396r-8(a)(1). Once a manufacturer enters a rebate agreement with CMS, state Medicaid programs are required, with certain limited exceptions, to reimburse providers for that manufacturer's drugs. 42 U.S.C. § 1396r-8(d).

98. Pursuant to the Rebate Statute, drug manufacturers (including Abbott, Dey and Roxane) are required to calculate and submit AMPs to CMS on at least a quarterly basis. 42 U.S.C. § 1396r-8(b)(3) and (k)(1).

99. CMS administers the Rebate Statute in part by using a manufacturer's AMP information and drug utilization information submitted by States to calculate a "Unit Rebate Amount" (URA). 42 U.S.C. § 1396r-8(b)(2)(A). The URA is the unit amount computed by CMS to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due. Reid Decl., Exhibit 34 at p. 5.

100. The Rebate Statute requires that AMPs provided to CMS be kept confidential and not be disclosed by CMS except for the purpose of carrying out the purposes of the rebate program. 42 U.S.C. § 1396r-8(b)(3)(D).

101. The specific rebate agreements entered into between CMS and the defendants state as follows:

> Pursuant to Section 1927(b)(3)(D) of the [Social Security] Act and this Agreement, information disclosed by the Manufacturer in connection with this Agreement is confidential and, notwithstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices changed by the Manufacturer, except as

> necessary by the Secretary to carry out provisions of [the Rebate Statute].

(Roxane SOF, Tab 143, p. 9; Reid Decl., Exhibit 34)

102. In a 1995 proposed rulemaking published at 60 Fed. Reg. 48442 (1995), the Department of Health and Human Services stated as follows concerning AMP information:

> C. Confidentiality of Manufacturer Price Information
>
> Comment: Many of the commenters believed that States should not have access to manufacturers' price information, including unit rebate amounts, since HCFA has access to this information. The commenters stated that the risk of disclosure and use of information for other purposes is too great.
>
> Response: We have agreed not to disclose AMP and best price to States but maintain that the statute contemplates the disclosure of manufacturer pricing data to States. Section 1927(b)(3)(D) of the Act provides that information concerning drug prices must not be disclosed by "the Secretary or a State agency (or contractor therewith)." By including States within the confidentiality provisions, we believe that the Congress intended that States have the right to access of sufficient pricing information to calculate their rebates as required by the statute. The unit rebate amount, which provides the rebate due per tablet, etc., and which is the end result of the manufacturer's calculation, is, in our opinion, the minimum amount of information States need to accomplish this. At the same time, the statute protects the manufacturer's pricing data from disclosure. In accordance with section 1927(b)(3)(D) of the Act, information disclosed by manufacturers in connection with the rebate agreement is confidential and, notwithstanding other provisions of law (including the Freedom of Information Act, 5 U.S.C. 552) must not be disclosed by HCFA, the State agency, or its contractors in a form that reveals the manufacturer, except as necessary for the Secretary of HHS to carry out the provisions of section 1927 and for the Comptroller General or the Director of the Congressional Budget Office to review the information provided.

103. In an exchanged of letters in October 1991 and May 1992 relating to the State of Hawaii's implementation of the Medicaid Rebate statute, HCFA requested, and Hawaii gave

assurances that “the State will keep the unit rebate amount confidential and will not disclose it for purposes other than rebate invoicing and verification." (Henderson Common Exhibits 27 and 28)

104. On or about April 22, 2004, CMS approved a New Hampshire State Plan Amendment allowing the State to enter into the Michigan Multi-State Pooling Supplemental Drug Rebate Agreement. The SPA included the statement, “[t]he unit rebate amount is confidential and cannot be disclosed in accordance with Section 1927(b)(3)(D) of the Social Security Act.” (Henderson Common Exhibit 29; Dey Exhibit 95)

105. A copy of the Michigan Multi-State Pooling Supplemental Drug Rebate Agreement signed by Dey (and which Dey marked “HIGHLY CONFIDENTIAL”) states, “The unit rebate amount is confidential and cannot be disclosed in accordance with Section 1927(b)(3)(D) of the Social Security Act.” Paragraph 7.3 of the Agreement states, "The parties further agree that any information provided to the state by the manufacturer pursuant to this agreement and this agreement itself constitute trade secrets and other confidential or proprietary commercial and financial information not subject to public disclosure." The Agreement includes a “Schedule 3" which states that the Supplemental Rebate Amount is calculated based in part on the “CMS Unit Rebate Amount.” (Henderson Common Exhibit 30; Dey Exhibit 96)

106. In a September 2001 “Medicaid Drug Rebate Operational Training Guide” prepared by CMS’s Center for Medicaid and State Operations, the agency stated that AMPs:

> are generally subject to both privacy and trade secret restrictions and are not released by CMS and must not be released by states. The pricing data CMS receives is held in the strictest confidence, and must not be released by states. The pricing data CMS receives is held in the strictest confidence and maintained only on CMS’s

> master files. CMS sends URAs to states, but actual pricing data goes no farther than CMS.

(Roxane SOF, Tab 142A, at D2)

107. In a letter to the State of Texas dated May 3, 2004, CMS stated:

> You ask for confirmation that State Medicaid programs may not use the rebate information, including the Unit Rebate Amount (URA) and Reconciliation of State Invoice (ROSI) reports, to calculate an estimated acquisition cost (EAC) for reimbursement. You are correct. In light of the confidentiality provisions of Section 1927(b)(3)(D) of the Social Security Act, drug pricing information disclosed by manufacturers pursuant to the drug rebate provisions is confidential and shall not be disclosed by either the Secretary or the State.

(Henderson Common Exhibit 31)

108. In a statement submitted to the Subcommittee on Health Care of the Senate Finance Committee on or about March 14, 2002, CMS Administrator Thomas Scully stated, "We collect AMP data for Medicaid on one side of my agency. . . . But by statute we're not allowed to share that with the Medicare side of the agency. It's proprietary data just for the purpose of the Medicaid program. . . . . the law that created it prohibited us from using AMP for Medicare. . . . . AMP provides a pretty good source of data, but by statute it is limited to use for the Medicaid program and the Medicare side of my agency doesn't have access to it by law." "Reimbursement and Access to Prescription Drugs Under Medicare Part B," 107th Cong. 16, Hearing Before the Subcomm. on Health Care of the S. Finance Comm. (March 14, 2002) (statement of Thomas A. Scully), 2002 WL 399357 at *18-19.

109. Larry Reed, Technical Director in the Division of Pharmacy, CMS, testified regarding AMP information submitted by manufacturers, stating, "The information that we would get from the manufacturers would not be part of the reimbursement system. The information that we get from the manufacturers would be part of the rebate program, the AMP data, the best price data." (Henderson Common Exhibit 32 (10/2/08 Reed Dep.), at 1094:4-9)

110. Responsible officials at CMS testified that understood AMPs were confidential, and could only be used for purposes of the Rebate Program. *See, e.g.* (Henderson Common Exhibit 33 (9/26/2007 Reed Dep.), at 282:20 - 283:4; Henderson Common Exhibit 34 (9/27/2007 Reed Dep.), at 352:14 - 353:11; Henderson Common Exhibit 35 (6/21/2007 Vladeck Dep.), at 457:19 - 460:20, 464:7 - 464:19, 584:21 - 586:4; Henderson Common Exhibit 36 (2/27/2007 Duzor Dep.), at 368:14 - 369:10)

111. AMPs were not utilized in the calculation of Federal Upper Limits, as AMPs were not listed in "published compendia." 42 C.F.R. § 447.332(a)(1)(ii); Henderson Common Exhibit 40 (Declaration of Susan Gaston), ¶ 6 [Exhibits omitted]. Persons responsible for setting FULs at CMS did not use AMPs, as AMPS are not listed in "published compendia." *Id.*; Henderson Common Exhibit 37 (3/19/2008 Gaston Dep.), at 528:4 - 529:1)

112. AMPs were on occasion provided to HHS, Office of the Inspector General, in furtherance of the OIG's mission to conduct audits and investigations, and to prevent and detect waste, fraud and abuse in the agency's programs and operations. 5 U.S.C. app. 3 §§ 2, 4, 8G (1988). However, responsible officials at OIG testified that

they understood AMPs were confidential. (Henderson Common Exhibit 38 (2/6/2008 Vito Dep.), at 1196:10 - 1196:19) OIG and other governmental reports regularly referred to AMPs as confidential. Roxane SOF, Tab 91, at 20, Box 2 ("the average manufacturer price (AMP), used to calculate the Medicaid rebate, is not public information"); Roxane SOF, Tab 146, p.3 (Section 1927(b)(3)D) of the Social Security Act requires that, subject to certain exceptions, AMPs reported to CMS not be publicly disclosed)

113. CMS did not instruct states to use AMPs for reimbursement. (Henderson Common Exhibit 33 (9/26/2007 Reed Dep.), at 281:16-22)

114. State Medicaid officials have testified that they understood that AMPs were confidential, and that they could not use AMP information in setting reimbursement rates. (Henderson Common Exhibit 19 (12/10/2008 Bridges Dep. (Arkansas)), p. 70:5 - 72:22; Henderson Common Exhibit 43 (12/3/2008 Gorospe Dep. (California)), at 283:8 - 284:21; Henderson Common Exhibit 11 (12/15/2008 Dubberly Dep. (Georgia)), at 83:20 - 86:18; Henderson Common Exhibit 12 (11/18/2008 Parker Dep. (Illinois)), at 72:2 - 74:8; Henderson Common Exhibit 21 (10/28/2008 Farrand Dep. (New Hampshire)), at 287:1 - 293:17; Henderson Common Exhibit 14 (12/2/2008 Vaccaro Dep. (New Jersey)), at 77:1 - 77:16, 102:18 - 103:19; Henderson Common Exhibit 16 (10/21/2008 Weeks Dep. (North Carolina)), at 112:8 -113:10; Henderson Common Exhibit 17 (12/15/2008 Rugg Dep. (Vermont)), at 373:1 - 373:20)

115. In a 2001 report, the OIG discussed the confidentiality of the AMPs as follows:

> Currently, CMS interprets the confidentiality clause very narrowly. This interpretation prevents CMS from sharing average manufacturer price data

> with State Medicaid agencies. The CMS reports only the unit rebate amounts to States, from which States cannot deduce AMP because of the complex unit rebate methodology. It would seem plausible, however, to interpret the confidentiality provision more broadly as a safeguard to prevent manufacturers from gaining access to the pricing information of their competitors. The legislation specifically prohibits the State Medicaid agencies from disclosing average manufacturer price and Best Price, which implies a legislative assumption that State Medicaid agencies would have access to that information. In September 1995, CMS addressed this issue in response to comments received on the proposed rule regarding Medicaid payment for outpatient drugs. The CMS asserted that they would not to disclose AMP to the States but maintained that the statute contemplates the disclosure of manufacturer pricing data to the States and that they believed Congress intended that States have access to sufficient pricing information to implement the Medicaid drug rebate program.

(Reid Decl., Ex. 38, at 22)

V. DAMAGES

A. Medicaid Data

116. Dr. Duggan, the United States damages expert, relied upon multiple sources of Medicaid data. One category is data that was collected directly from the states in connection with this litigation. The other source was data was collected by the CMS directly from the states in connection with CMS' administration of the Medicaid program. The state data in CMS' possession is of two types. One is known as the State Drug Utilization Data (SDUD). The other category includes three similar types of data known as the Medicaid Analytic Extract (MAX) data, the State Medicaid Research Files (SMRF) and the Medicaid Statistical Information System (MSIS). This data is similar and is generally referred to together as SMRF/MAX or SMRF/MAX/MSIS. The combination of the datasets provided Dr. Duggan with claims data from all 50 states. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 12-16)

117. For various reasons, including need, timing, and resources, Dr. Duggan did not perform a claim by claim analysis of all of the data collected from the individual states. However, Dr. Duggan did use the data from the additional states in other ways, for example, to help evaluate which were the best states to include in the claim by claim analysis, and to help validate the SMRF/MAX/MSIS/SDUD data. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 17)

118. For Dr. Duggan's Medicaid analyses, he utilized claims data obtained directly from state Medicaid agencies for 10 states in Dr. Duggan's Abbott analysis, 14 states for Dr. Duggan's Dey analysis and 16 states in Dr. Duggan's Roxane analysis. The data from these states accounted for between 63 and 68 percent of all claims for the defendants Complaint products. The remainder of Dr. Duggan's analysis relied upon the data collected from the states by CMS. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 17)

119. The SDUD and SMRF/MAX data pertained to varying time periods for all 50 states plus the District of Columbia, and overlapped substantially with each other and with the data obtained directly from the states. The overlap in the data sets allowed Dr. Duggan to validate the accuracy of each data set through a review and comparison of each so that only data determined to be reliable was utilized. Dr. Duggan found no material variations between the datasets. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 18)

120. Dr. Duggan never calculated any damages except where he had data that was directly based upon claims submitted to the state Medicaid programs which he had

evaluated for reliability and concluded was reliable. In order to further improve upon the reliability of his results, Dr. Duggan performed various reviews. For example, he checked each claim contained in the data acquired directly from the states to verify its accuracy by seeing if he could replicate the amount paid. Data that was found to not match a state's methodology, or that was otherwise questionable was not used in Dr. Duggan's analysis. As a result, Dr. Duggan discarded large amounts of data that likely would have increased the calculated damages. (Henderson Common Exhibit 41 (Duggan Decl.), ¶19)

B. Medicare Data

121. For his Medicare Damages analysis, Dr. Duggan reviewed a complete set of Medicare J-code billing data, obtained directly from CMS. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 21)

122. Dr. Duggan analyzed the J-code data separately for the durable medical equipment (DME) claims and for the Medicare Part B claims which generally represent drugs administered incident to the care of a physician. The vast majority of DME claims were processed by a total of four DME carriers at any one time. The DME carriers are called Durable Medical Equipment Regional Carriers or "DMERCs". (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 21)

123. The Part B claims were processed by a greater number of carriers. The individual Part B carriers are identified by a total of 92 different codes, though in many cases the same carrier has multiple codes. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 21)

124. The payment amounts for each HCPCS J-code are determined by each DME and Part B insurance carrier (*e.g.* Palmetto) in accordance with instructions from CMS with the typical carrier using the median AWP of the NDCs included in the carrier's array as the per-unit allowed amount, with this changing to 95 percent of the median on January 1, 1998. The particular NDCs that are included in an array vary across carriers and can vary within the same carrier over time. Carriers sometimes shared arrays, or the resulting calculations, and did not always prepare new arrays if there were no changes to the prices. However, a complete set of the arrays used by every carrier to select the medians for each J-code for each time period was not available for Dr. Duggan's use. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 22)

125. There are three parts to Dr. Duggan's analysis of the Medicare claims. First, he reviewed the claims processed by Medicare under the DME benefit. These DME claims were processed by the DMERCs. Dr. Duggan has array information that applies to more than 90 percent of the claims for these DME claims and, as he detailed in his expert report, he dropped those claims for which he was unable to replicate the allowed amount from the claim from the array documents. There was no need to extrapolate in connection with the DME claims. (Henderson Common Exhibit 41 (Duggan Decl.) ¶ 23)

126. Second, Dr. Duggan reviewed the claims processed by regular Medicare Part B carriers in situations where he had at least some of the arrays. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 24)

127. Third, Dr. Duggan reviewed claims processed by regular Medicare Part B carriers for which he did not have the arrays. He performed separate damage calculations for each. The second and third steps were only necessary for his analysis of the Abbott claims. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 24)

C. Damages Analysis

128. There were several steps to Dr. Duggan's actual damage calculations. The first step was to calculate the average selling price of the defendants' products using the defendants' own transaction data. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 29-36) He then used the results of that analysis to determine the amounts that would have been paid by Medicare and Medicaid in reliance upon those transaction based prices. (*Id.*, ¶ 25)

129. Dr. Duggan directly calculated Medicaid damages on a claim by claim basis using data acquired directly from the ten states for Abbott, fourteen states for Dey and sixteen states for Roxane representing 63% to 68% of the total dollars paid on the defendants' drugs. He extrapolated from that amount to calculate a relatively modest amount of additional damages for those same ten, fourteen or sixteen states. Dr. Duggan also extrapolated from that amount to the other states plus the District of Columbia to calculate additional damages. (Henderson Common Exhibit 41 (Duggan Decl.) ¶¶ 26, 37-38)

130. Dr. Duggan directly calculated Medicare damages on the DME claims where Dr. Duggan had 90% of the arrays for all three defendants. (Henderson Common Exhibit 41 (Duggan Decl.) ¶ 27)

131. For Abbott, on the Part B claims where Dr. Duggan had some arrays he performed a calculation of damages. Dr. Duggan used that damage calculation as a basis for calculating damages associated with the other Part B carriers. (Henderson Common Exhibit 41 (Duggan Decl.), ¶28)

132. The manner in which Dr. Duggan calculated damages for Medicare is straightforward. If, for example, defendants had one product in a particular carrier's array for one of the HCPCS codes listed in the Complaint, then that price would be substituted in the array to see if the median price from that array would change. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 49)

133. Dr. Duggan repeated this exercise for all of the arrays located from the carriers, and this allowed me to estimate how Medicare spending would have changed if alternative prices had been used for defendants' products' AWPs. More specifically, if using 125 percent of defendant's average transaction prices as the AWP for defendants' NDCs would reduce the median, Dr. Duggan replaced the per-package price used by the carriers in adjudicating the claim with the revised median. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 53)

134. Dr. Duggan repeated the foregoing process for each of the carriers for each of the defendants. It is important to emphasize that the dollar figure for the damages does not account for the effect on the co-payments of Medicare recipients. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 54)

135. In the Abbott analysis, with respect to the Part B carriers, Dr. Duggan performed this analysis for Connecticut General, Wisconsin Physician Services, certain

other Region 5 carriers that shared the arrays with Wisconsin Physician Services, Kentucky Administar, West Virginia Nationwide, other Metra Health and Florida Blue Shield. (During the latter several years of the study period, seven other carriers operating in CMS Region 5 – Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin – used the allowed amounts from the WPS arrays described above. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 55)

D. Extrapolation

136. Extrapolation is simply described as a way to estimate by projecting known data. Extrapolation is a tool used by economists even if complete and perfect data exists. This is the case because use of all data is often time consuming or prohibitive and unnecessary. There are acceptable methods of extrapolation and Dr. Duggan has used them in this case. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 56)

137. Dr. Duggan had various data sets for use. The fact that Dr. Duggan did not have state-produced claims data for some states did not mean Dr. Duggan did not have state claims data. As Dr. Duggan explained above, CMS had state claims data collected from earlier state productions in a form different than the individual claims data provided by the states during the litigation. In fact, if states were unable or unwilling to produce in litigation their individual claims data, Dr, Duggan believes he still could have performed a reasonable estimate of damages in this case from the state data collected by CMS. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 58)

1. Medicaid Extrapolation

138. Dr. Duggan's use of extrapolation – to a reasonable degree of economic certainty – arrived at a reasonable approximation of the damages, or difference between (1) what the federal government reimbursed for certain pharmaceutical products dispensed to Medicaid recipients during the relevant period, and (2) what the federal government would have reimbursed for the same drugs during the same time period if prices reflective of the actual prices at which defendants were transacting business had been reported by defendants. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 60)

139. As Dr. Duggan describes in his declaration, not all states directly produced all of the claims data for all of the drug products at issue. As an supplement, Dr. Duggan used claims data that the states provided to CMS in connection with the normal operations of the Medicaid program, some of which was claims-level data and some of which was aggregated data. Aggregated data describes high-level data that is composed of a multitude or combination of other more individual data. The use of such aggregated data does not diminish the reliability or validity of the damages estimate Dr. Duggan calculated. As an economist, Dr. Duggan is trained in methods of using aggregated data when individual data is unavailable or prohibitive and unnecessary, all of which was true in this litigation. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 62)

140. For the remainder of the states, Dr. Duggan used the information regarding the 10, 14 or 16 states as the basis for estimating the additional damages. The extrapolation from the 10, 14 or 16 states to the other states was reasonable for at least the following several reasons. First, Dr. Duggan extrapolated only to those periods for which he had claims data that he found to be reliable. Second, Dr. Duggan used data for

more than one thousand combinations of NDC quarters when estimating the damages associated with the other states. Third, for 10, 14 or 16 states, Dr. Duggan ran his analysis on a claim by claim basis. His extrapolations were based on his detailed analysis of this large proportion of the overall claims (63% to 68% of the total paid for the defendants' Complaint NDCs) and his methodology allowed me to re-adjudicate each of those millions of claims. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 63-64)

141. As an economist, Dr. Duggan found this method to be more optimal than a traditional random sample, which would have been a review of a smaller fraction of those claims. Dr. Duggan also concluded his review was also a better method than sampling each NDC for each state for each year which could have required thousands of separate samples with numerous sample claims in each sample; such an approach would have been near impossible and fewer claims would have been reviewed. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 64)

142. In many circumstances Dr. Duggan had detailed state data and other aggregated data from for the same time periods. When he compared data obtained directly from the states to this other data, he found the data from CMS was reliable because there were no significant variations between the two and because the total dollars and units generally matched. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 65)

143. In addition, Dr. Duggan examined all of the data which he relied upon to assess its quality. For example, Dr. Duggan reviewed every claim in the data collected from the states to confirm that he could replicate the amount paid. This was a detailed review. For example, Dr. Duggan's examination of the data provided by Indiana

revealed it to be unreliable, and I therefore did not use it in Dr. Duggan's analysis. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 66)

144. Dr. Duggan had also claims data from over 30 states which covered at least part of the relevant time period, and he performed a general review of this data to confirm that it was consistent with his other findings. Dr. Duggan chose not to use all of the state data in his possession to perform detailed claim by claim calculations because it was prohibitive or duplicative and unnecessary. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 67) By focusing on the 10, 14 or 16 states, he was able to perform a higher quality review of the state claims data which served as the basis for the extrapolation. The state pharmacy reimbursement methodologies for the 10, 14 or 16 states were very similar to the state pharmacy reimbursement methodologies for the 40 states. (*Id.*, ¶ 68) The average amounts paid for each NDC by the 10, 14 or 16 states were very similar across the 10, 14 or 16 states. The average amounts paid for each NDC by the 10, 14 or 16 states were also very similar to the average amounts paid for each NDC by the other states. (*Id.*, ¶ 69)

145. Dr. Duggan eliminated a substantial number of claims which did not precisely match the expected reimbursement and the damages on those claims were assumed to be zero even though it is likely that there were some damages associated with those claims. Dr. Duggan made numerous downward adjustments in the scope and magnitude of my extrapolations that would more than offset the magnitude of any differences between the 10, 14 or 16 states and the other states. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 70)

146. As Dr. Duggan calculated the damages in this case, he performed many different tests to confirm that the data was suitable for the purposes at hand. Thus, there were numerous checks done to confirm that each of the data sets was reliable and could be used in the manner that he used them. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 72)

147. Defendants and their experts posit that extrapolations can only be done in connection with routine random samples, or routine disproportionate random stratified samples of the type typically done when examining the claims of a single provider over the course of a single year. While the typical way to select a representative, non-biased sample is through randomization, a sample can still be representative and non-biased even if not selected through a random process. Dr. Duggan chose to focus on the largest states to obtain the maximum amount of precision. As Dr. Duggan explain in a rebuttal report, it is more important to the total value of the damages to be as accurate as possible for the state of Florida, than it is in the state of Vermont. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 73-74)

148. One quite simple, but significant component of the extrapolation that Dr. Duggan performed (as is true for any extrapolation) is that it is based on averages. Thus, assuming one has done the types of checks that Dr. Duggan has done, the variables that would tend to raise the damages figures are balanced by the variables that would tend to lower the damages figures. On average, of course, the number is reliable. A criticism based solely upon cherry picking examples of the variables that would tend to raise the damages figures without factoring in the variables that would tend to lower the damages

figures is not reliable. Rather, such biased criticism suffers from the exact same type of flaw that the defense experts allege to be the supposed problem Dr. Duggan's analysis. A key difference is that his analysis considered both sides of the equation, whereas the defendant's experts appear to only or primarily consider the side of the equation that benefits defendants. There are numerous examples throughout Dr. Duggan's analysis of adjustments that reduce the amount of the damages that he have calculated, and those adjustments more than offset any of the alleged shortcomings leveled by the defendants. In addition, defense experts' criticisms are leveled without the benefit of any actual quantification of the supposed impact, so they are unhelpful. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 76)

a. Intra-State Extrapolation

149. In certain periods for each of these 10, 14 or 16 states, Dr. Duggan did not have complete state claims data collected directly from the states. However, that data was generally very complete. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 77)

150. In Dr. Duggan's Abbott analysis, the data for the 10 states accounted for approximately 86.8 percent of the claims. Thus, Dr. Duggan used the SMRF/MAX/MSIS for 8.7 percent of the claims data from CMS and aggregate SDUD data from CMS for an additional 4.5 percent. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 78)

151. In Dr. Duggan's Dey analysis, the data for the 14 states accounted for approximately 82.1 percent of the claims. Thus, Dr. Duggan used the SMRF/MAX/MSIS for 8.9 percent of the claims data from CMS and aggregate SDUD

data from CMS for an additional 9.0 percent. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 79)

152. In Dr. Duggan's Roxane analysis, the data for the 16 states accounted for approximately 93.5 percent of the claims. Thus, Dr. Duggan used the SMRF/MAX/MSIS for 4.3 percent of the claims data from CMS and aggregate SDUD data from CMS for an additional 2.3 percent. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 80)

153. As a check on his approach on this issue, for each of the five largest states for which Dr. Duggan performed within-state extrapolations in the Abbott case (Florida, California, New Jersey, New York, and Kentucky) and for each of the states used in the Dey and Roxane cases, Dr. Duggan assumed for the sake of the calculation that the state Medicaid claims data started one year later than they actually did. He then utilized the SMRF/MAX/MSIS claims data if it was available and otherwise used the SDUD data to estimate the total value of the damages during these one-year periods. Dr. Duggan's findings indicate that the total value of the damages is actually substantially higher when he used the claims data collected directly from the states compared to when he extrapolated using the SDUD and SMRF/MAX/MSIS claims data. The fact that Dr. Duggan did not have complete state Medicaid claims data collected directly from the states for the entire eleven-year period for these states reduced rather than increased the total value of the damages. His extrapolation therefore inured to the benefit of the defendant. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 82)

b. Inter-State Extrapolation

In connection with his extrapolation from the 10, 14 or 16 states to the other states, Dr. Duggan also performed various additional checks. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 83-85)

154. Dr. Duggan used multiple sources of detailed information regarding Medicaid claims for the drugs at issue for those states to which he was extrapolating. Additionally, Dr. Duggan did not extrapolate to any state or time period in which he did not have any CMS data (claims information from the state or SDUD data). (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 86)

155. The algorithm Dr. Duggan used was very straightforward. He began his analysis of each of the other state's SMRF / MAX data by applying inclusion criteria analogous to those described above for the 10, 14 or 16 preceding states. For example, he dropped claims with a paid amount of zero or with a strictly positive third party payment amount. Dr. Duggan then aggregated the number of claims and total Medicaid spending for each state by NDC-quarter. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 89)

156. Dr. Duggan then merged this claims data for each of the remaining states to a data set in which the unit of observation was the NDC-quarter and that was constructed using the 10, 14 or 16 states' Medicaid claims data described above. For each NDC-quarter, Dr. Duggan first calculated the average fraction of claims with a difference greater than zero across all 10, 14 or 16 states. Dr. Duggan also calculated the average value of the ratio of the difference to the amount of Medicaid spending on these

claims. In calculating these averages, Dr. Duggan weighted each of the 10, 14 or 16 states that had data for that NDC-quarter equally, while states with no claims data for that NDC-quarter have a weight of zero. These averages then were used in his algorithm. Dr. Duggan followed a similar algorithm for the SDUD data. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 90)

2. Medicare Extrapolation

157. Dr. Duggan's use of extrapolation – to a reasonable degree of economic certainty – arrived at a reasonable approximation of the Medicare damages, or difference, between (1) what the federal government reimbursed for certain pharmaceutical products dispensed to Medicare recipients during the relevant period, and (2) what the federal government would have reimbursed for the same drugs during the same time period if prices reflective of the actual prices at which defendants were transacting business had been reported by defendants. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 91)

158. For all three defendants, his analysis of the Medicare claims based upon the carriers and carrier periods with arrays was reasonable for at least the following reasons. First, all carriers were hired by CMS to perform the same job, received the same instructions from CMS, and used the same price source – Red Book. Second, for those arrays Dr. Duggan did use in my analysis, one of defendants' products was included in almost every case. Third, Dr. Duggan eliminated a substantial number of claims which did not precisely match the expected reimbursement, and he assumed the damages on those claims were zero even though it is likely that there were some damages associated

with them. An assumption that there were no damages for the other carriers is more likely to be wrong by a larger margin than these results. Finally, Dr. Duggan analyzed carrier array practices and did not see any evidence from defense or otherwise that carriers used different approaches in cases where he had arrays than in cases where he did not have arrays. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 92-93)

159. For Dr. Duggan's Abbott analysis, the extrapolation based upon the Part B carriers and carrier periods with arrays was reasonable for at least the following reasons. First, for the time periods where Dr. Duggan had arrays, the damages he calculated were in an amount equal to 28.5% of the total payments by Medicare on those drugs. Due to Dr. Duggan's various conservative adjustments in cases where he did not have the arrays, the damages were only 16.1% of the total payments. Second, in claims during time periods for which Dr. Duggan did not have arrays, the allowed amount is equal to the published price of an Abbott product over 1.3 million times, thereby demonstrating that an Abbott product had to have been in the array. Second, Dr. Duggan did not calculate damages regarding 7 of the 12 Complaint J-codes, which account for more than 11 percent of Medicare spending on Complaint J-codes. For the DME claims, Dr. Duggan restricted attention to just the J3370 code, which reduced the difference he calculated below what it would have been if he had considered the other ten J-codes (especially J7051) as well. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 94)

160. For the DME carrier damages, Dr. Duggan had array information that applied to more than 90 percent of the claims during the time in which almost all of the claims were paid. As Dr. Duggan explained in his expert reports, he dropped those

claims for which he was unable to replicate the allowed amount from the claim from the array documents. Thus, Dr. Duggan performed no extrapolation in connection with the DME claims. For Abbott , it is also important to note that the total damages Dr. Duggan calculated was conservative because he dropped DME claims for all of the several J-codes. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 95-96)

3. Part B Claims for Abbott Analysis

161. To calculate the damages in circumstances where the arrays were not available, Dr. Duggan used results from the carriers for which he had array information to conduct analyses analogous to those in the preceding sections for the remaining carriers. Before doing this, Dr. Duggan first considered the Medicare Part B claims for all carriers to determine whether the two groups were comparable. The data suggested that the amount paid per claim for each J-code, the pattern of spending over time, and the proportion of claims accounted for by each of the five J-codes is quite similar. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 97)

162. Dr. Duggan also determined the frequency with which each of the two groups had an Abbott NDC's AWP (or 95 percent of its AWP) as the allowed amount per unit. Dr. Duggan did this to investigate whether other carriers used Abbott NDC's as frequently in their arrays during the time period of interest. For example, Dr. Duggan found that 24.41 percent of Medicare claims administered by CG and the other carriers described above had an Abbott AWP as the allowed amount during the 1995Q3 (the first quarter for which Dr. Duggan had arrays for multiple products) to 2001Q4 period. The corresponding fraction for all other carriers is 18.44 percent. Dr. Duggan adjusted my

estimates for the remaining carriers to account for the fact that the Medicare claims data indicated they used Abbott NDCs somewhat less frequently than CIGNA and the other carriers above. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 98)

163. To estimate the number of claims for these remaining carriers with a value of the difference that is greater than zero and the total value of the difference, Dr. Duggan used an algorithm analogous to others he used and described in detail in his expert reports. Specifically, for the total value of the difference, Dr. Duggan multiplied NDC-specific total Medicare spending by these carriers by the ratio of the difference to the total amount of Medicare spending for the carriers for this same NDC. Dr. Duggan then deflated this value to account for the fact that these other carriers less frequently had Abbott AWPs as their allowed amounts. Dr. Duggan considered the 1993Q1 to 2001Q4 period for these remaining carriers (thus ignoring 1991 and 1992), and calculated the number of provider payments with at least one claim with a value of difference that exceeded zero as described for the other Medicare carriers above. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 99-100)

164. The total value of the difference was $15.708 million, which represents 16.7 percent of the total amount spent by these carriers. This is lower than the corresponding ratio of 22.9 percent from Table 43 in his report because he scaled down the difference as described above. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 101)

165. As above, the value of the difference does not account for the effect on Medicare recipients' co-payments amounts. Additionally, Dr. Duggan has excluded 6 of

the 11 J-codes from consideration, with these six accounting for approximately 4.5 million carrier claims and 11.0 percent of spending for the remaining carriers. This latter adjustment served to reduce the total value of the difference below what it would be if Dr. Duggan considered all eleven J-codes in the Complaint. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 102)

166. As indicated in Table 35 of his June 19, 2008 report, Dr. Duggan had array information for 21 of the 91 carriers listed. Of the 6.172 million claims for the 21 carriers for which Dr. Duggan did have some array information, Dr. Duggan had array information from carrier documents for 3.590 million (58.2 percent) of them. Because these carriers tended to be significantly larger than the average, they accounted for a disproportionate share (40 percent) of Medicare carrier claims for the five J-codes that he considered. This fraction is much greater than economists frequently have for analyses of government programs. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 103-104)

167. Dr. Duggan extrapolated back in time for additional claims. Before doing this, however, Dr. Duggan examined the claims data to check that there was some evidence that the carrier was using Abbott products in its arrays by checking whether an Abbott product's AWP is the allowed amount in some cases. When there was little evidence to suggest that Abbott products appeared in the AWP, Dr. Duggan dropped the claims from consideration, which led him to drop 590,000 (9.6 percent) of the claims for these 21 carriers. After dropping these claims, Dr. Duggan applied an extrapolation methodology for the Medicare carrier claims that was analogous to the one described

above for the 10 Medicaid states. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 104-105)

168. As for the remaining 70 carriers, which accounted for 60 percent of Medicare carrier claims for the five J-codes that Dr. Duggan considered, Dr. Duggan applied an extrapolation methodology that was similar to the across-state one that I used for the Medicaid analyses. For more than 1.3 million claims for these 70 carriers, Dr. Duggan was certain that an Abbott product was included in the array because its AWP was the allowed amount and no other firm's product typically had that same AWP at the same time. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 106, 108)

169. Dr. Duggan's examination of the Medicare claims data for the two groups of carriers (the 21 and the 70) indicated that the amount paid per claim for each J-code, the pattern of spending over time, and the proportion of claims accounted for by each of the five J-codes was similar. However, Dr. Duggan's analyses also indicated that the frequency with which the seventy carriers used Abbott products in their arrays appeared to be lower. More specifically, Dr. Duggan found that 24.4 percent of the claims administered by the 21 carriers had an Abbott AWP as the allowed amount versus just 18.4 percent of the claims paid by the remaining 70 carriers. Dr. Duggan therefore adjusted my estimates for these 70 carriers downward to account for this factor. Using an appropriate and transparent methodology to adjust my difference results for the 21 carriers to the remaining 70, Dr. Duggan found that the ratio of the difference to spending for the remaining 70 was substantially lower for this latter group. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 106, 109)

Respectfully submitted,

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